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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,449	03/28/2000	KATSUMI AOYAGI	594.352USWO	8016

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EXAMINER
WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
1648	14

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/509,449	AOYAGI ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1-7 were canceled and new claims 8-17 were added in Paper No. 13, the original of which was submitted on April 22, 2002.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is indefinite because it recites "HCV" without explanation. For clarity, an abbreviated term should be spelled out in full the first time it appears in the claims.

Claim 12 is confusing because it recites "from position 100 to position 130 of an HCV polypeptide" and "from position 1 to position 42 of the HCV polypeptide." Numbered positions with respect to any HCV "polypeptide" are not sufficient to specify what regions are being claimed. Further, while applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "HCV polypeptide" in claim 12 is used by the claim to mean "the HCV polyprotein," i.e., the entire, unprocessed protein that is encoded by the HCV genome, while the accepted meaning of "HCV polypeptide" is any polypeptide that is encoded by the HCV genome.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-17 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Claims lacking certain features critical or essential to the practice of the invention, but not included in the claims, are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

In particular, the specification states at page 15, lines 11-15: "Namely, to construct an assay system which simultaneously detects HCV antigen and HCV antibodies, the same antigen, i.e., the core antigen must be used for both the antigen detection system and the antibody detection system";

at page 16, lines 11-14: "Therefore, it is important that an antigen for detection of antibodies against the HCV epitopes has a sequence from the position 1 to the position 40 and from the position 66 to the position 80 of the HCV polypeptide";

at page 16, line 29-page 17, line 9: "On the other hand, for the detection of antigen, monoclonal antibodies recognizing and binding to the region from the position 100 to the position 130 of the HCV polypeptide, antibodies against which region are relatively rare in specimens, is used as a primary antibody, and to detect the core antigen captured by the primary antibody, a monoclonal antibody recognizing a region from the position 40 to the position 50 of the HCV polypeptide, which region is not used for the detection of antibody, is used as a secondary antibody.

"Both the above-mentioned monoclonal antibodies do not bind to the antigenic region from the position 1 to the position 42 of the HCV polypeptide, which is used for the detection of HCV antibodies, and therefore by using the above-mentioned

antibodies and antigen, no reaction interference occurs in the antigen system, and both the detection systems can simultaneously function."

It is apparent from the cited portions of the specification that, in order to practice a method for determining the presence of HCV antigens and/or anti-HCV antibodies in a sample, at the same time, in the same reaction vessel, as recited in claim 8, it is essential to use an antigenic peptide that has from position 1 to position 40 of the HCV polyprotein, and from the position 66 to the position 80 of the HCV polyprotein, together with antibodies that specifically bind to the region from position 100 to position 130 of the HCV polyprotein as a primary antibody, and a monoclonal antibody recognizing a region from position 40 to position 50 of the HCV polyprotein, which region is not used for the detection of antibody, as a secondary antibody, wherein the antibodies that bind specifically to HCV antigen do not specifically bind the antigenic peptide that binds specifically to anti-HCV antibodies. Since the specification indicates that these features are critical or essential to practice of the invention, claims not reciting these essential features are not enabled.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Aoyagi et al. (Journal of Clinical Microbiology 37(6):1802-1808, June 1999), of record,

essentially for reasons of record in rejecting claims 1-7 in the previous Office action. Aoyagi et al. disclose an immunoassay method for detecting hepatitis C core antigen in the presence of Triton X-100, CHAPS, and SDS in a sample pretreated with the same composition (see, e.g., page 1803, column 1, "Specimen pretreatment and EIA for HCVcAg"), and also disclose measuring anti-HCV antibodies by their binding with HCV polypeptides (see, e.g., page 1803, paragraph bridging column 1 and column 2, "EIA for anti-HCV core antibodies").

Claims 8-17 are rejected under 35 U.S.C. 102(a) as being anticipated by WO99/06836, of record, published 2/11/99, essentially for reasons of record in rejecting claims 1-7 in the previous Office action. The Abstract discloses "a method for assaying a virus antigen and a virus antibody in the presence of a surfactant which has alkyl having 10 or more carbon atoms and a secondary, tertiary or quaternary amine and/or a nonionic surfactant on the basis of the bonds to the probes thereof," and HCV is disclosed in the body of the document, as well as the English version of the title ("Method for Detection or Measurement of Hepatitis C Virus") that appears at the beginning of the sequence listing, thus anticipating the subject matter of claims 8-17.

Applicant cannot rely upon the foreign priority papers to overcome these rejections because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Applicant has indicated that a verified translation is being prepared and will be filed; since no translation has been received, that rejections under 35 U.S.C. 102(a) are maintained.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/133007. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant claims 8-17 and claims 1-7 of Application No. 10/133007 are drawn to a method of detecting HCV antigen and HCV antibodies in a sample, in the presence of one or more detergents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

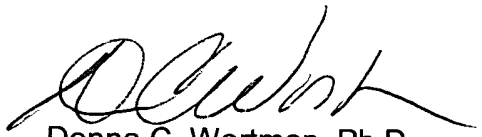
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
January 9, 2003